

Applicants respectfully traverse and request that the rejection be withdrawn in view of the following remarks.

The presently claimed method is directed to a method for the therapy of chronic pelvic cavity pain syndrome due to urinary dysfunction. Claim 1 recites a method for the therapy of chronic pelvic cavity pain syndrome which consists essentially of administering an effective therapeutic dose of tamsulosin or a pharmaceutically acceptable salt thereof to a subject in need of such therapy, wherein the chronic pelvic cavity pain syndrome is caused by urinary dysfunction.

Claim 2 is directed to a method for the therapy of hypogastric/perineal pain or lower backache which consists essentially of administering an effective therapeutic dose of tamsulosin or a pharmaceutically acceptable salt thereof to a subject in need of such therapy, wherein the hypogastric/perineal pain or lower backache is caused by a state of decreased urine production.

Abrams is directed to a dose-ranging study of the efficacy and safety of tamsulosin, the first prostate-selective α_{1A} -adrenoceptor antagonist in patients with benign prostatic obstruction. The objective in Abrams is to evaluate efficacy and safety of tamsulosin for the patient suffering from Lower Urinary Tract Symptoms (LUTS) associated with Benign Prostatic Hyperplasia (BPH). The primary aim of the study was to determine the optimum dosage of tamsulosin to be administered in phase III clinical studies.

The indices used in Abrams for evaluating the efficacy and safety of tamsulosin were urodynamic and urinary symptoms. These symptoms were assessed using a modified Boyarsky symptom score, which consists of eight symptoms; i.e., daytime frequency, nocturia, urge incontinence, urgency, hesitancy, reduced urinary stream, terminal dribbling, feeling of

incomplete bladder emptying. These symptoms were graded on a six point scale from 0 to 5. See, Abrams, lines 2 to 8 of the right column of page 589.

Applicants respectfully submit that Abrams does not teach or suggest an index for evaluations which directly or indirectly relate to pain. Throughout the study, safety was assessed by monitoring adverse effects such as, blood pressure and pulse rate; i.e., vital signs. Additionally, laboratory variables, such as haematology, biochemistry and urine analysis were also assessed. See, Abrams, p. 589 at lines 20-24. According to Abrams, patients were also asked about the occurrences of specific series of pre-determined symptoms, such as dizziness, nasal stuffiness, blurred vision, dizziness on change of posture, skin rash, change in bowel habit, sore gums, joint pains, sleepiness, and ringing in the ears. See, Abrams, page 587 at lines 20 to 29. According to Abrams, pain and headache were reported as side effects as shown in Table 3 on page 592 of Abrams.

Applicant respectfully submit that the difference between the present claimed method and the teachings of the prior art is that Abrams neither teaches or suggests a method for the therapy of chronic pelvic pain syndrome or a method for the therapy of hypogastric/perineal pain or lower backache comprising the administration of tamsulosin. Thus, although Abrams teaches that pain and headaches are an adverse side effect of the administration of tamsulosin, a person of ordinary skill in the art would expect improvement of pain as a therapeutic effect of the administration of tamsulosin based on the teachings in Abrams. In fact, Abrams teaches away from the inventions recited in present claims 6 and 7. Accordingly, claims 6 and 7 are not rendered obvious over Abrams. Accordingly, Applicants request that the rejection be withdrawn.

II. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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